



## Patient Information Sheet

### Isotretinoin (marketed as Accutane)

This is a summary of the most important information about isotretinoin. For details, talk to your healthcare professional.

**FDA ALERT [05/2005]: FDA continues to assess reports of suicide or suicide attempts associated with the use of isotretinoin. All patients treated with isotretinoin should be observed closely for symptoms of depression or suicidal thoughts, such as sad mood, irritability, anger, loss of pleasure or interest in social or sports activities, sleeping too much or too little, changes in weight or appetite, school or work performance going down, or trouble concentrating.**

*This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.*

#### What Is Isotretinoin?

Isotretinoin is used to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. If untreated, nodular acne can lead to permanent scars. However, because isotretinoin can have serious side effects, you should talk with your healthcare professional about all of the possible treatments for your acne and whether isotretinoin's possible benefits outweigh its possible risks.

#### Who Should Not Take Isotretinoin?

You should not take isotretinoin if you:

- Are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment
- Are breast-feeding
- Do not completely understand its possible risks and are not willing to follow all of the instructions given by your healthcare professional.
- Are sensitive to isotretinoin or parabens, which are used as preservatives in the gelatin capsule.

#### What Are The Risks?

**Isotretinoin should NOT be used by pregnant women.**

- **Suicide potential:** See the FDA Alert above.
- **Birth defects (deformed babies):** Do not use if pregnant, or plan to get pregnant in the next month. If you get pregnant while taking Isotretinoin, stop taking it right away and call your healthcare professional. Women using Isotretinoin must use 2 separate forms of birth control for at least a month before taking Isotretinoin, during treatment, and one month after taking Isotretinoin.
- **An increased pressure in your brain**, possibly leading to permanent loss of sight, or in rare cases, death. Symptoms include bad headache, blurred vision, dizziness, nausea or vomiting, seizures (convulsions) or stroke.
- **Organ damage** of the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach).
- Bones, muscles, and ligaments damage
- Hearing problems
- Vision problems

- High cholesterol and triglycerides (blood fats)
- **Isotretinoin may cause other problems.** Tell your healthcare professional if you have any other serious or unusual problems.

#### What Should I Do Before Using Isotretinoin?

- Before starting isotretinoin, tell your healthcare professional if you or someone in your family has had any kind of mental problems, asthma, liver disease, diabetes, heart disease, osteoporosis (bone loss), weak bones, anorexia nervosa (an eating disorder where people eat too little), or any other important health problems.
- Also tell your prescriber about any food or drug allergies you have had in the past.

Female patients of childbearing potential must:

- Have negative results from 2 pregnancy tests before receiving the initial isotretinoin prescription.
- Have a negative pregnancy test before each refill
- Sign a Patient Information/Consent form that contains warnings about the risk of potential birth defects if the fetus is exposed to isotretinoin
- Be informed of the purpose and importance of participating in the Isotretinoin Survey and be given the opportunity to enroll

#### Are There Any Interactions With Drugs Or Foods?

Tell your healthcare professional about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Isotretinoin and other medicines may affect each other, causing serious side effects. Especially tell your healthcare professional if you take:

- Birth control pills that do not contain estrogen ("minipills")
- Vitamin A supplements
- An oral or injected corticosteroid or anticonvulsant (seizure) medication
- Antibiotics
- St. John's Wart or other supplements

#### Is There Anything Else I Need to Know?

**Never give your isotretinoin to anyone else. It may not be the right treatment for them. Also, it would be dangerous if the other person is pregnant or gets pregnant.**

- You will only be able to get up to a 30-day supply of isotretinoin at one time. Refills will require you to get a new written prescription from your doctor with a yellow Isotretinoin sticker. The prescription must be filled within 7 days.
- You should receive an Isotretinoin Medication Guide each time you receive Isotretinoin. This is required by law.
- Do not give blood while you take isotretinoin and for 1 month after stopping Isotretinoin. If someone who is pregnant gets your donated blood, her baby may be exposed to isotretinoin and may be born with birth defects.
- Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, while you are using Isotretinoin and for at least 6 months after you stop. Isotretinoin can increase your chance of scarring from these procedures.
- Avoid sunlight and ultraviolet lights as much as possible. Tanning machines use ultraviolet lights. Follow up with your doctor every month during therapy and for one month after therapy, as well as anytime you have concerns.

Accutane FDA Approved 1982

Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570

Druginfo@cder.fda.gov





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